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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,356	10/29/2003	Kenneth F. Buechler	071949-2705	7520

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EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,356	BUECHLER, KENNETH F.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 8/2/2006 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 11-16 are cancelled.
2. Claims 1-10 and 17 are under examination.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 1, 8 and 17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 11-19 of U.S. Patent No. 5947124. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim drawn to a method for determining the ratio of oxidized cardiac troponin I to reduced cardiac troponin I in a myocardial infraction patient's sample by using two antibodies where the first antibody can recognize both oxidized and reduced form of troponin I, and the second antibody can bind to either one of the oxidized and reduced first-antibody-troponin I complex, but do not form a complex with other said oxidized or reduced cardiac troponin I in the sample. The cited US 5947124 patent directs to a method of measuring a ratio of oxidized to reduced troponin I in a blood sample of myocardial infraction patients (claim 1) by using distinct components specific for troponin I (claim 12) where one of the distinct components is specific for both at least one oxidized form of troponin I and at least one of reduced form of troponin I (claim 15 and 19), and a second antibody is specific for either at least one oxidized form of troponin I, or at least one reduced form of troponin I (claim 13-14, 17-18). The performance is conducted for establishing a standard curve for analysis (claim 11).

Response to Applicant's Arguments

Double Patenting

The nonstatutory double patenting rejection of claims 1, 8 and 17 against US Patent 5.947,124 (abbreviated as 124' patent) are maintained. The rejection of claim 9 is withdrawn because 124' patent does not disclose use of a normalizing factor calculated using known ratios of oxidized and reduced cardiac troponin I.

Applicant argues that the 124' patent fails to disclose several critical claim elements as to the instant claims. For instance, applicant indicates that 124' patent does not describe any single assay where one determines the ratio of oxidized to reduced cardiac troponin I. Applicant argues that the 124' patent determines the ratio of oxidized and reduced cardiac troponin I by measuring

two of the following three concentrations: (1) concentration of oxidized form; (2) concentration of reduced form and (3) concentration of total (oxidized and reduced) form. Furthermore applicant also argues that 124' patent fails to disclose the feature of "first antibody that binds oxidized and reduced cardiac troponin I in an amount proportional to their ratio in the sample." Applicant also argues that the 124' patent fails to disclose that a complex containing two different antibodies is formed in the assay.

Applicant arguments have been considered, but are not persuasive.

The 124' patent discloses substantially identical invention as recited in the current claims which fulfills the criteria set forth in the judicially created doctrine grounded in public policy (nonstatutory double patenting) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. The main issue is whether examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). supra.

The 124' patent discloses measuring several concentrations of troponin I as what applicant had described. However, these different concentrations can also be viewed as in a single assay with different steps as recited in the current claim 1. The languages used in 124' patent does not preclude using in a single assay by measuring these different concentrations of troponin I.

With respect to the feature of "first antibody that binds oxidized and reduced cardiac troponin I in an amount proportional to their ratio in the sample", it is an inherent characteristic of the binding antibody. Note, the antibodies used in both 124' patent and the current application are the same (incorporated by reference WO 96/33415). Thus, it would be inherent to have the recited feature.

With respect to the complex formed by the antibodies, as discussed before, it is also an inherent characteristic when antigen bound to the antibody that complex would form.

Applicant also argues that the "standard curve for analysis" of current claim 8 is different from the "standard curve" recited by 124' patent where the standard curve in 124' patent is used to correlate a measured ratio of oxidized to reduced troponin I to determine the time of myocardial infraction. The standard curve used in claim 8 is to correlate a measured assay signal to determine the ratio of oxidized to reduced troponin I.

Applicant arguments have been considered, but are not persuasive.

The measuring of the ratio of oxidized to reduced troponin I is essential to both the 124' patent and the current application. Although 124' patent correlate the ratio to the time of myocardial infraction, it is still the same step of operation to measure the ratio of these two proteins, i.e. oxidized and reduced form of troponin I.

Claim Rejections - 35 USC § 102

The rejections of claims 1-10 and 17 as being anticipated under 35 USC 102 (e) by Buechler et al. are withdrawn because applicant had submitted recordation of common ownership. However, the "Non-Statutory Double Patenting" rejection remains effective.

Applicant argues that the Chart-II B is not relevant because applicant had established common ownership and Chart-II A. Nevertheless, *assuming arguendo*, applicant is still entitled to the protection of common ownership because common ownership does not impact a rejection under 102 (e).

Applicant arguments have been considered, but are not persuasive.

As indicated by the examiner the rejection of 102 (e) is withdrawn in view of establishment of common ownership under Chart-II B. The reason is that the current invention and the 124' patent are NOT the SAME invention. That is why Chart-II B is followed.

Otherwise a *"Statutory Double Patenting"* would be issued under Chart-II A. Furthermore, even if Chart-II A is used as suggested by the applicant, the 102 (e) rejection is still appropriate under common ownership because 124' patent has a *different inventive entity*, i.e. Paul McPerson (emphasis added). At any event, the 102 (e) rejection is withdrawn and the Non-Statutory Double Patenting is maintained.

Conclusion

3. No claim is allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu
Examiner
Art Unit 1641

October 6, 2006

LONG V. LE 10/12/06
SUPERVISORY PATENT EXAMINER
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